

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TENNESSEE  
AT KNOXVILLE**

**UNIVERSITY OF TENNESSEE RESEARCH  
FOUNDATION,**

*Plaintiff,*

v.

**CAELUM BIOSCIENCES, INC.,**

*Defendant.*

**No. 3:19-cv-00508-CLC-HBG**

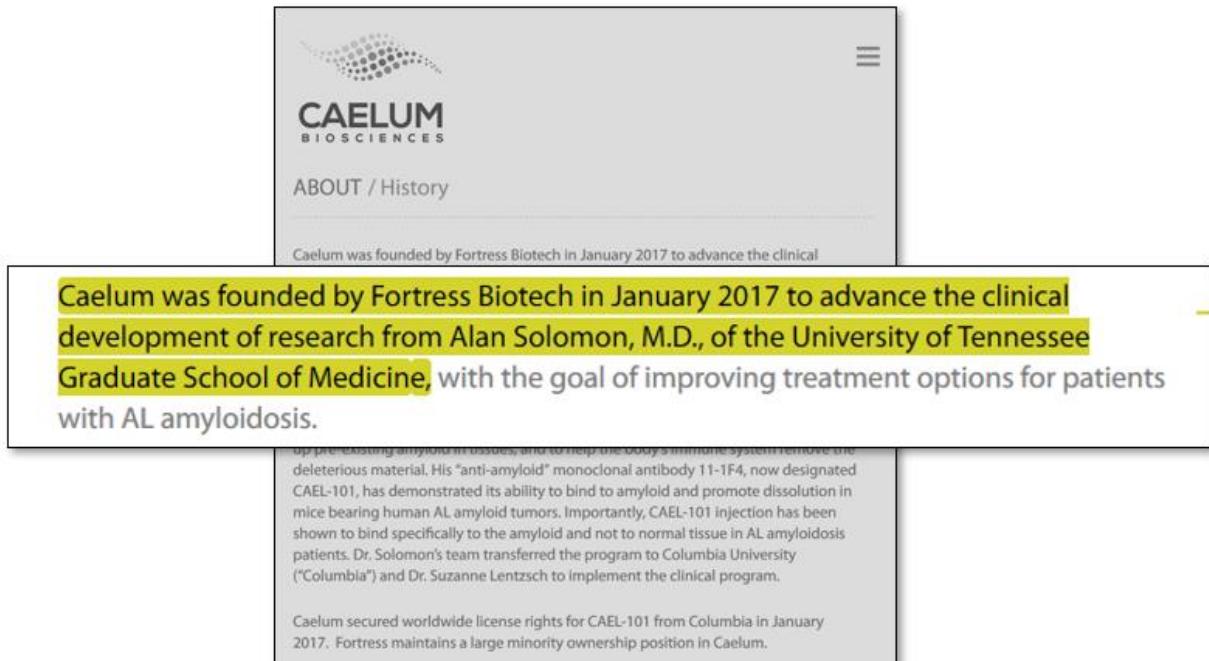
**JURY TRIAL DEMANDED**

**FIRST AMENDED COMPLAINT**

University of Tennessee Research Foundation (“UTRF” or “Plaintiff”) brings this action for breach of contract, conversion, tortious interference with contract, tortious interference with business relations, slander of title, unjust enrichment, and misappropriation of trade secrets against Defendant Caelum Biosciences, Inc. (“Caelum” or “Defendant”) arising from Caelum’s unlawful possession and use of a groundbreaking monoclonal antibody and related research materials developed by Dr. Alan Solomon, Emeritus Professor at The University of Tennessee Graduate School of Medicine and former head of the Human Immunology and Cancer Research Program.

**INTRODUCTION**

1. Caelum is commercializing an antibody used for the treatment of amyloidosis that it does not own. The antibody was developed by Dr. Alan Solomon of The University of Tennessee and the ownership of the antibody materials and associated research materials are held by University of Tennessee Research Foundation. Caelum has refused to compensate UTRF for its use of the antibody despite repeatedly recognizing that Caelum was “founded . . . to advance the clinical development of research from Alan Solomon, M.D., of The University of Tennessee Graduate School of Medicine.”



*About Caelum Biosciences, CAELUM BIOSCIENCES WEBSITE* (last visited November 2019) (emphasis added), available at: <https://www.caelumbio.com/about/history/>.

2. Caelum continues to evade compensating UTRF for its development of 11-1F4 while simultaneously boasting of Caelum's close relationship to the work of The University of Tennessee. "CAEL-101 which is also referred to as 11-1F4, that was the original name of the compound emanated from the University of Tennessee and the University of Tennessee actually really initiated the whole development process of treatments to attack the Amyloid and they started about 20 years ago." *Caelum Biosciences CEO Michael Spector Interview: Looking for a Better Alternative to Chemotherapy for AL Amyloidosis*, THE BIO REPORT TRANSCRIPT at 8:29-8:45 (2018).

3. In the mid-to-late 1990s, Dr. Solomon created the 11-1F4 antibody and discovered its effectiveness in treating amyloidosis while working as a professor and researcher for The University of Tennessee. Caelum has repeatedly acknowledged that the 11-1F4 antibody was developed by Dr. Solomon while at The University of Tennessee.

Dr. Solomon pioneered early development of antibodies that work to break up pre-existing amyloid in tissues, and to help the body's immune system remove the deleterious material. His “anti-amyloid” monoclonal antibody 11-1F4, now designated CAEL-101, has demonstrated its ability to bind to amyloid and promote dissolution in mice bearing human AL amyloid tumors.

*About Caelum BioSciences, CAELUM BIOSCIENCES WEBSITE* (last visited November 2019) (emphasis added), available at: <https://www.caelumbio.com/about/history/>.

4. Dr. Solomon and his colleagues Drs. Rudi Hrncic and Jonathan Wall, who were also employed as faculty members at The University of Tennessee, conducted early-stage research on the 11-1F4 antibody and its applications in helping to fight amyloidosis.

5. Shortly after Dr. Solomon and his colleagues' discovery of the anti-amyloid effects of the 11-1F4 antibody, Dr. Solomon and his colleagues filed an invention disclosure and executed an agreement and assignment, assigning all right, title, and interest in the 11-1F4 antibody technology to The University of Tennessee Research Corporation (now UTRF).<sup>1</sup>

6. Despite UTRF's continued ownership of the 11-1F4 technology, Caelum has publicly claimed that it holds the “worldwide license rights” to 11-1F4. Based on these representations Caelum has secured significant monetary compensation including an agreement for payments of up to \$500 million dollars based on the success of the 11-1F4 technology.

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<sup>1</sup> In 2003, The University of Tennessee Research Corporation was renamed and reorganized under its current name, University of Tennessee Research Foundation (“UTRF”).



Alexion and Caelum Biosciences Announce Collaboration to Develop Targeted Therapy for Light Chain (AL) Amyloidosis

[View Release](#)

on Phase 2 data for pre-negotiated economics. Alexion will make payments to Caelum totaling up to \$60 million, including the purchase price for the equity and milestone-dependent development funding payments. The collaboration also provides for potential additional payments of up to \$500 million, including the upfront and regulatory and commercial milestone payments, in the event Alexion exercises the

January 31, 2019 06:30 AM Eastern Standard Time  
BOSTON & NEW YORK--(BUSINESS WIRE)--Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) and Caelum Biosciences today announced a collaboration to develop CAEL-101 for light chain (AL) amyloidosis. CAEL-101 is a first-in-class amyloid fibril targeted therapy designed to improve organ function by reducing or eliminating amyloid deposits in patients with AL amyloidosis. AL amyloidosis is a rare systemic disorder that causes misfolded immunoglobulin light chain protein to build up in and around tissues, resulting in progressive and widespread organ damage, most commonly to the heart and kidneys.

*Alexion and Caelum Biosciences Announce Collaboration to Develop Targeted Therapy for Light Chain (AL) Amyloidosis, PRESS RELEASE (January 31, 2019) (emphasis added), available at: <https://www.caelumbio.com/alexion-and-caelum-biosciences-announce-collaboration-to-develop-targeted-therapy-for-light-chain-al-amyloidosis>*

7. UTRF seeks monetary damages arising from Caelum's decision to take and develop a promising immunotherapy it knew belonged to Plaintiff without consulting or securing any rights for its development from UTRF.

#### THE PARTIES

##### UNIVERSITY OF TENNESSEE RESEARCH FOUNDATION

8. University of Tennessee Research Foundation is a non-profit 501(c)(3) organization that promotes, licenses, and commercializes The University of Tennessee's intellectual property.

9. Originally created in 1935 as The University of Tennessee Research Corporation, University of Tennessee Research Foundation helps The University of Tennessee fulfill its mission

in becoming a national leader in research, discovery, and innovation. University of Tennessee Research Foundation “was established to protect, manage, and commercialize university inventions and intellectual property; grow the university research enterprise; develop and support an entrepreneurial culture; and contribute to state and regional economic development.”<sup>2</sup>

10. Established in 1794, The University of Tennessee is Tennessee’s flagship public research institution based in Knoxville, Tennessee. The University of Tennessee has approximately 50,000 students<sup>3</sup> and over 360 degree programs.<sup>4</sup> As recently as 2017, The University of Tennessee system spent more than \$481 million directly on research and sponsored program expenditures.<sup>5</sup> To maximize the public benefit that its research generates, technological innovations developed by The University of Tennessee faculty are typically assigned to University of Tennessee Research Foundation, which commercializes these innovations on behalf of The University of Tennessee.

11. University of Tennessee Research Foundation is the second-oldest university research foundation in the United States. University of Tennessee Research Foundation’s mission is to promote, support, and carry out the research mission of The University of Tennessee, to enhance the competitive position of The University of Tennessee for research and development funding, facilitate expanded research and development activities at The University of Tennessee, and to facilitate the commercialization of University of Tennessee research outcomes and the

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<sup>2</sup> *State of Tennessee Comptroller of the Treasury*, THE UNIVERSITY OF TENNESSEE FINANCIAL AND COMPLIANCE AUDIT REPORT at 19 and 57 (January 20, 2015).

<sup>3</sup> THE UNIVERSITY OF TENNESSEE WEBSITE, available at: <https://tennessee.edu/about/>.

<sup>4</sup> THE UNIVERSITY OF TENNESSEE KNOXVILLE WEBSITE, available at: <https://admissions.utk.edu/study/programs-and-majors/>.

<sup>5</sup> THE UNIVERSITY OF TENNESSEE WEBSITE, available at: <https://tennessee.edu/about/>.

transfer of research-generated technology from The University of Tennessee to commercial and industrial enterprises in furtherance of the economic development of the State of Tennessee.

12. UTRF is responsible for licensing intellectual property covering University of Tennessee inventions and collecting royalties on behalf of The University of Tennessee from those license agreements. The State of Tennessee Comptroller has described the role of UTRF as:

The foundation's stated purpose is, in conjunction with the university, to grow the University of Tennessee research enterprise; harvest, manage, and market University of Tennessee intellectual property; encourage and support entrepreneurial education and ventures by faculty, staff, students, and commercial partners/affiliates of the University of Tennessee; and to contribute to the well-being of the State of Tennessee through economic development.

*The University of Tennessee Audit Report for The Year Ending June 30, 2014, STATE OF TENNESSEE COMPTROLLER OF THE TREASURY at 57 (January 20, 2015).*

13. Since its inception as The University of Tennessee Research Corporation in 1935, UTRF has been actively involved in licensing patents whose technologies were first developed at The University of Tennessee. The University of Tennessee Research Corporation's 1935 charter stated that its mission was "to promote, encourage and aid scientific social and/or educational investigation and research."<sup>6</sup> In furtherance of these objectives, the corporation was empowered "[t]o aid in the prosecution of applications for patents, registrations and/or copyrights, foreign and domestic . . . To prosecute infringements or invasions of any patent, trade-mark, trade name, brand, label, copyright or patent right in which the corporation may be interested."<sup>7</sup>

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<sup>6</sup> CHARTER OF INCORPORATION OF THE UNIVERSITY OF TENNESSEE RESEARCH CORPORATION (December 31, 1934).

<sup>7</sup> *Id.*



*Safer Aviation and Improved Fruits and Berries Also Engage the Ingenuity of American Inventors*, N.Y. TIMES at 20 (June 10, 1944) (Describing a patent “issued to Brooks D. Drain of Knoxville, Tenn., on a ‘healthy, prolific strawberry plant variety’” and “assigned to the University of Tennessee Research Corporation.”).

14. In its first decades of existence, The University of Tennessee Research Corporation licensed technologies relating to cottonseed, fruit varieties, and water treatment.

Of late, research on a small commercial scale is being carried on by the University of Tennessee Experiment Station and a *University of Tennessee Research Corporation* has been set up to license and control the use of the process. Here then we have a state institution of learning working with a federal government agency, a professional society, a trade association, and private capital all working together for a common purpose now by the upbuilding of regional agricultural economy.”<sup>8</sup>

The largest manufacturer of cottonseed manufacturing equipment in the United States has applied for a license under royalty to be paid to the University of Tennessee Research Corporation.<sup>9</sup>

The University of Tennessee Research Corporation licenses manufacturers to make equipment resulting from the research work for which a patent has been obtained or applied for.”<sup>10</sup>

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<sup>8</sup> THE UNIVERSITY OF TENNESSEE RECORD, Vol. 44, Issue 4 (1941).

<sup>9</sup> UNITED STATES CONGRESS JOINT COMMITTEE HEARING ON THE TENNESSEE VALLEY AUTHORITY at 1451 (1939).

<sup>10</sup> Statement of David E. Lilienthal, Chairman, Tennessee Valley Authority, TECHNOLOGICAL MOBILIZATION, HEARINGS BEFORE A SUBCOMMITTEE OF THE COMMITTEE ON MILITARY AFFAIRS OF THE UNITED STATES SENATE S. 2721 Vol. 3 at 910 (December 1942).

15. More recently, UTRF has licensed technologies in various fields of technology, including important, lifesaving technologies. UTRF has recently licensed patents for a vaccine for group A streptococcus (Strep-A) and for treatments for prostate cancer.<sup>11</sup>

**CAELUM BIOSCIENCES, INC.**

16. Caelum Biosciences, Inc. is a Delaware corporation with a principal place of business at 1200 Florence Road, Bordentown, New Jersey 08505. Caelum may be served with process by delivering a summons and a true and correct copy of this complaint to its registered agent for receipt of service of process, Incorporating Services, Ltd., 3500 S. DuPont Hwy, Dover, Delaware 19901. Caelum was first incorporated with the Delaware Secretary of State on June 10, 2015.

17. Caelum was founded by Fortress Biotech, Inc. which is an investment company that acquires rights in pharmaceutical products. “Our operations have been limited to acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of product candidates, and making investments in other companies.” FORTRESS BIOTECH 2017 ANNUAL REPORT at 15 (March 16, 2018).

18. Fortress Biotech, Inc. is a publicly traded company based in New York City, New York that has created a network of more than 10 “partner companies.” Caelum is one of these partner companies.

Caelum Biosciences, Inc. (“Caelum”), founded by Fortress Biotech, is a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases. Caelum’s lead asset, CAEL-101 (mAb 11-1F4), is a novel antibody for

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<sup>11</sup> James B. Dale, et al., *Potential Coverage of a Multivalent M Protein-Based Group a Streptococcal Vaccine*, VACCINE 31.12 (2013): 1576–1581 (“The University of Tennessee Research Corporation has licensed the technology to Vaxent, LLC.”); Tom Wilemon, *Powerful Possibilities: GTx Scientists Battle Time, Regulatory Setbacks to Make it Big*, MEMPHIS DAILY NEWS (May 17, 2010) (“The SARM patents, as well as Steiner’s research into tormifene for the prevention of prostate cancer, were licensed to GTx by the University of Tennessee.”).

the treatment of patients with amyloid light chain (“AL”) amyloidosis. Phase 1a/1b data presented at the American Society of Hematology’s 59th Annual Meeting in December 2017 support CAEL-101’s potential to be a safe and well-tolerated therapy that promotes amyloid resolution.

*Fortress Biotech Portfolio Companies – Caelum Biosciences*, FORTRESS BIOTECH WEBSITE (last visited November 2019) (emphasis added), available at: <https://www.fortressbiotech.com/portfolio-companies/caelum.cfm>.

19. Caelum was founded by Fortress Biotech after employees and/or agents at Fortress Biotech identified the 11-1F4 technology as a “new technolog[y] with clinical and commercial potential.” *Id.*

20. In a 2018 interview, Michael Spector, Caelum’s C.E.O., disclosed that in 2016 Fortress Biotech orchestrated to have Columbia University and Fortress Biotech execute a confidential option agreement to commercialize the 11-1F4 antibody. This secret option agreement was never disclosed to UTRF despite UTRF having an Inter-Institutional Agreement for Invention Management relating to the 11-1F4 antibody.

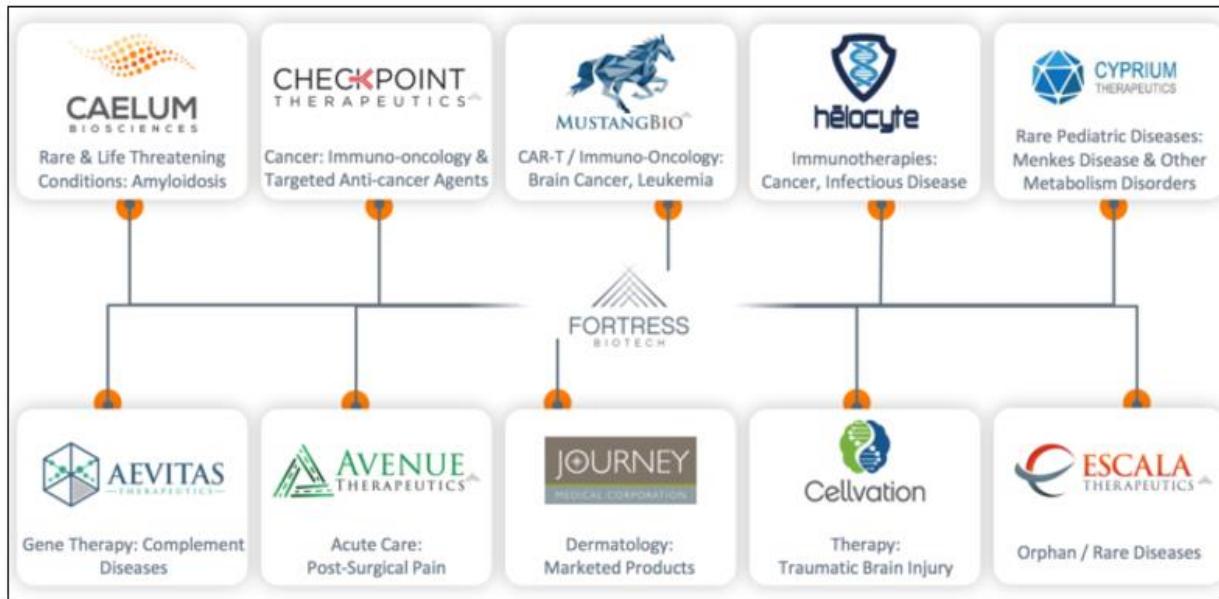
The original inventor Alan Solomon had the concept of directly treating the Amyloid deposits retired and transferred the program to Columbia University and Dr. Suzanne Lentzsch who was the principal investigator on the phase 1 trial. I had met Dr. Lentzsch probably in the first half of 2016 and I got to know her well and understand the work that she was doing with CAEL-101 at the time 11-1F4. There was some very very preliminary phase 1a data that had already been presented at the ASH meeting of 2015 which is the biggest hematology meeting in the United States. We were very excited about what we saw from the single dose portion of phase 1 . . . umm . . . and she was planning to present the full preliminary phase 1a data . . . sorry let me start over . . . Dr. Lynch was planning to present the phase 1a results as well as the phase 1b results at the ASH meeting in 2016. And so we had signed an agreement with Columbia University - an option agreement giving us the right prior to her presentation in 2016 because we saw the potential of this as a future treatment and we wanted to hit the ground running in 2017 after the ASH meeting. We exercised our option in early 2017.”

*Caelum Biosciences CEO Michael Spector Interview: Looking for a Better Alternative to Chemotherapy for AL Amyloidosis*, THE BIO REPORT TRANSCRIPT at 8:47-10:27 (2018) (emphasis added).

21. Fortress Biotech and its partner companies do not undertake original pharmaceutical research. Rather, Fortress Biotech describes itself as an “innovative

biopharmaceutical company focused on identifying, in-licensing and developing high-potential clinical stage assets.” <https://www.fortressbiotech.com/about-us/> (last visited November 2019).

Fortress Biotech explains its investment philosophy as “therapeutic area agnostic . . . allowing [Fortress] to invest in a broad array of new technologies . . .” *Id.*



*Fortress Biotech Portfolio Companies*, FORTRESS BIOTECH WEBSITE, available at: <https://www.fortressbiotech.com/portfolio-companies.cfm> (last visited Nov. 2019).

#### JURISDICTION AND VENUE

22. The United States District Court for the Eastern District of Tennessee has jurisdiction and venue over this matter because there is complete diversity and the amount in controversy exceeds \$75,000 and UTRF is a non-profit 501(c)(3) organization residing in Knox County, Tennessee.

23. This Court has personal jurisdiction over Caelum based on Caelum’s purposeful activities directed to this District that give rise to the claims in this case.

24. Caelum has entered into agreements with UTRF and The University of Tennessee exclusively relating to 11-1F4, which give rise to the claims at issue in this case. For example, on March 14, 2017, Caelum, UTRF, and The University of Tennessee entered into a contract that

states, “This Agreement is deemed to have been made in the State of Tennessee, United States of America, and shall be interpreted and construed and any legal relations created hereunder shall be determined in accordance with the laws of the State of Tennessee without giving effect to any conflict of laws provisions thereof.” On July 22, 2019, Caelum entered into a research agreement with The University of Tennessee. The July 22, 2019 Agreement is signed by Susan Sobolov, Caelum’s Chief Operating Officer, and states “This Agreement is made and entered into in the State of Tennessee and its validity and interpretation and the legal relations of the parties shall be governed by the laws of the State of Tennessee.” The July 22, 2019 Agreement covers the “Preclinical Evaluation of Amyloid Binding and Opsonization Using the Chimeric 11-1F4 Antibody.”

25. The 11-1F4 antibody and the data, property, and associated regulatory filings all originated with Dr. Alan Solomon, The University of Tennessee, and are all owned by UTRF. As Caelum acknowledges, “Alan Solomon, M.D., Professor of Medicine Emeritus and a former American Cancer Society Clinical Research Professor at the University of Tennessee Graduate School of Medicine[] pioneered early development of antibodies . . . and oversaw preclinical research on CAEL-101 [also known as 11-1F4].” *Fortress Biotech forms a new subsidiary, Caelum Biosciences, Inc., to develop a novel treatment for AL Amyloidosis*, PRESS RELEASE (Jan. 4, 2017).

26. The 11-1F4 information and materials at issue in this case originated at The University of Tennessee. The President of Alexion Pharmaceuticals—a minority owner of Caelum and the owner of an option to acquire all of Caelum—explained in a 2019 presentation that Alexion decided to invest in Caelum based on Caelum providing “data” that had been “generated at the

University of Tennessee.” Caelum knew that a substantial quantity of the 11-1F4 data it had taken was from The University of Tennessee.

So the reason we're really excited about CAEL-101 is it's an antibody that is specifically designed to bind to the kappa and lambda light chains of immunoglobulin. And when we looked at the data that the company had generated and researchers had generated in the University of Tennessee and at Columbia University and we looked at the in vivo imaging data, that gave us a lot of confidence because we could actually see that this antibody is binding to the amyloid deposits in the organs.

*Alexion Pharmaceuticals, Inc. Investor Day Presentation, CCBN FAIR DISCLOSURE WIRE TRANSCRIPT (March 20, 2019) (emphasis added).*

27. The sole focus and mission of Caelum is to commercialize the 11-1F4 technology, which it has renamed CAEL-101. Caelum’s website states: “Caelum was founded by Fortress Biotech in January 2017 to advance the clinical development of research from Alan Solomon, M.D., of the University of Tennessee Graduate School of Medicine, with the goal of improving treatment options for patients with AL amyloidosis.” *About Caelum Biosciences, CAELUM BIOSCIENCES WEBSITE* (last visited November 2019), available at: <https://www.caelumbio.com/about/history/>. Upon its founding, Caelum’s parent company, Fortress Biotech, announced “the formation of a new subsidiary company, Caelum Biosciences, Inc., to advance the development of CAEL-101 (11-1F4).” *Fortress Biotech forms a new subsidiary, Caelum Biosciences, Inc., to develop a novel treatment for AL Amyloidosis, PRESS RELEASE* (Jan. 4, 2017) (emphasis added); *see also Pipeline, CAELUM BIOSCIENCES WEBSITE* (last visited February 2020), available at: <https://www.caelumbio.com/pipeline/> (identifying only “CAEL-101,” (Caelum’s renaming of 11-1F4) as the only product in Caelum’s product pipeline).

28. The claims in this case all arise from ownership claims to an antibody that Caelum itself recognizes was developed in and came from Tennessee.

Alan Solomon, M.D., Professor of Medicine Emeritus and a former American Cancer Society Clinical Research Professor at the University of Tennessee Graduate School of Medicine, who pioneered early development of antibodies that work to break up pre-existing amyloid in tissues and oversaw preclinical research on CAEL-101.

*Fortress Biotech Forms New Subsidiary, Caelum Biosciences, Inc., To Develop Novel Treatment For Al Amyloidosis, CAELUM PRESS RELEASE (January 4, 2017).*

Caelum was founded by Fortress Biotech in January 2017 to advance the clinical development of research from Alan Solomon, M.D., of the University of Tennessee Graduate School of Medicine, with the goal of improving treatment options for patients with AL amyloidosis.

*Caelum About / History, CAELUM BIOSCIENCES WEBSITE, available at:*  
<https://www.caelumbio.com/about/history/>.

29. Caelum's interest and pursuit of the 11-1F4 technology has repeatedly taken it to Knoxville, Tennessee. Executives from Caelum have met with at least Drs. Solomon and Wall as well as UTRF personnel at University of Tennessee facilities on several occasions to discuss in-person various aspects of the 11-1F4 technology.

30. Caelum executives traveled to Knoxville and conducted meetings with personnel from UTRF and/or The University of Tennessee on at least the following occasions: on September 6, 2017, Caelum CEO Michael Spector met with personnel from both UTRF and The University of Tennessee; on October 11, 2017, Mr. Spector and additional Caelum personnel met with personnel from both UTRF and The University of Tennessee; and on November 8, 2019, Mr. Spector and Susan Sobolov, both of Caelum, met with personnel from The University of Tennessee. Each of these meetings occurred in conference room facilities at The University of Tennessee Medical Center, located in Knoxville, Tennessee.

31. Caelum employees also attended the American Society of Echocardiography (ASE) 29th Annual Scientific Session from June 22-26, 2018, in Nashville, Tennessee. There, Columbia University presented "a complete analysis of cardiac data from the Phase 1b trial of CAEL-101

(mAB11-1F4) for the treatment of relapsed or refractory amyloid light chain ('AL') amyloidosis" at the American Society of Echocardiography Scientific Sessions. *Caelum Biosciences Announces Presentation of Complete Cardiac Data Analysis from Phase 1b Trial of CAEL-101 in AL Amyloidosis at American Society of Echocardiography 29th Annual Scientific Sessions*, PRESS RELEASE (June 18, 2018).

32. Caelum has solicited and hired individuals located in this judicial District to serve on its scientific advisory board. For example, on February 22, 2018, Caelum entered into a Scientific Advisory Board Member Agreement with Dr. Alan Solomon. The Agreement identifies Dr. Solomon as residing in Knoxville, Tennessee and was executed by Caelum's C.E.O., Michael Spector. The scientific advisory agreement was entered into for the purpose of commercializing the 11-1F4 technology, which is owned by Plaintiff UTRF, and which is at issue in this case.

33. Further highlighting Caelum's ties to the State of Tennessee, and this judicial District in particular, Caelum has posted presentations on its website containing images taken from Dr. Solomon and Dr. Wall's laboratory at The University of Tennessee. For example, a 2017 presentation entitled "Personalizing Amyloidosis Therapy with Real Time PET Imaging of Fibril-Reactive Chimeric Antibody CAEL-101," which is available on the Caelum website at: <https://www.caelumbio.com/wp-content/uploads/2017/02/ASH-2018-12-3-Fu.pdf> contains numerous images that are credited: "Alan Solomon and Jonathan Wall Lab."

34. In addition to taking information, materials, and data out of this District, Caelum also sends materials into this District as part of its 11-1F4-related business. Pursuant to a 2019 Research Agreement, Caelum sent c11-1F4 and control chimeric antibodies to researchers in Knoxville, Tennessee for testing. These materials are the subject of UTRF's claim against

Caelum; Caelum's own transmission of these materials into this judicial District confers this Court with jurisdiction over Caelum.

35. This Court has personal jurisdiction over Caelum in this action because Caelum has committed acts within the Eastern District of Tennessee giving rise to this action and has established minimum contacts with this forum such that the exercise of jurisdiction over Caelum would not offend traditional notions of fair play and substantial justice.

#### **FACTUAL BACKGROUND**

#### **DEVELOPMENT OF THE 11-1F4 MONOCLONAL ANTIBODY TECHNOLOGY**

36. Dr. Solomon and his colleagues at The University of Tennessee first created the 11-1F4 antibody and discovered its anti-amyloid effects in the mid-to-late 1990s. Dr. Solomon is presently a Professor Emeritus at The University of Tennessee Graduate School of Medicine. During his distinguished career as a leader in the fields of immunology and cancer research, Dr. Solomon held National Institutes of Health grants for four decades and led groundbreaking research efforts to find effective treatments for devastating, fatal diseases, including amyloidosis – a difficult-to-diagnose, fatal, and rare disease. In addition to Dr. Solomon's leadership as an academic researcher, he has helped educate future generations of medical researchers and clinical physicians by serving as a Professor in the Department of Medicine and as the Director of the Human Immunology and Cancer Research Program within The University of Tennessee's Graduate School of Medicine. Dr. Solomon also helped countless patients through his decades-long clinical medical practice.

37. Among Dr. Solomon's research interests is the treatment of amyloidosis, a rare disease in which amyloids build up over time on critical human organs, such as the heart, brain, liver, and kidneys. Amyloidosis is often fatal as it leads to deterioration, and eventually organ failure. Patients often have as little as 9-36 months to live after being diagnosed with amyloidosis.

38. Shortly after Dr. Solomon and his colleagues' discovery of the anti-amyloid effects of the 11-1F4 antibody, Dr. Solomon and his colleagues Drs. Rudi Hrncic and Jonathan Wall filed a patent application that led to U.S. Patent No. 8,105,594. This patent covered certain methods of amyloid removal using anti-amyloid antibodies.

39. UTRF's predecessor, The University of Tennessee Research Corporation ("UTRC") promptly took ownership of not only the patent rights, but the 11-1F4 property rights and all know-how relating to the synthesizing and use of the antibody were transferred to UTRC by Dr. Solomon and his colleagues. Drs. Solomon, Hrncic and Wall filed invention disclosures and executed agreements and assignments assigning all 11-1F4 property rights to UTRC.

40. The 11-1F4 property rights and know-how transferred to UTRC by Drs. Solomon, Hrncic, and Wall's agreements and assignments include: all 11-1F4 antibody products (including all non-human, chimeric, humanized, and human versions, as well as analogs, variants, fragments of such versions), formulations, and conjugates thereof; the chimeric 11-1F4 antibody; cell clones utilized in the production of the chimeric 11-1F4 antibody; all know-how associated with the development and use of the antibody products, including the results, data, information and materials relating to antigens, antibodies, and cell lines necessary or useful for development or commercialization of the 11-1F4 antibody products; research data utilized in the Investigational New Drug application file submitted with the U.S. Food and Drug Administration in connection with an approval request for 11-1F4 therapies (including IND No. 117,316 entitled, "Chimeric Monoclonal Antibody 11-1F4"); and the Orphan Drug Designations for 11-1F4 issued by the U.S. Food and Drug Administration.

41. In 2003, UTRC was reorganized into UTRF. UTRF is the owner of all right, title, and interest in the 11-1F4 technology identified in the preceding paragraph.

## **THE 11-1F4 ANTIBODY IS DESIGNATED AN ORPHAN DRUG**

42. In 2009, Dr. Solomon applied for and received two different orphan drug designations for two indications of the 11-1F4 antibody (“the 11-1F4 Orphan Drug Designations”).

43. The 11-1F4 Orphan Drug Designations have considerable value. The 11-1F4 Orphan Drug Designations provide the holder a variety of financial and tax incentives, the most significant of which is a seven-year market exclusivity period for 11-1F4 therapies that receive market approval by the U.S. Food and Drug Administration for indications covered by the orphan drug designations.

44. In December 2009, the U.S. Department of Health and Human Services granted orphan-drug designation request #09-2937, which provides orphan-drug designation of monoclonal antibody 11-1F4 for use as a radioimmunoimaging agent in amyloidosis pursuant to 21 U.S.C. § 360bb.

45. Also in December 2009, the U.S. Department of Health and Human Services granted orphan-drug designation request #09-2903, which provides orphan-drug designation of monoclonal antibody 11-1F4 for use as a therapeutic agent in amyloidosis pursuant to 21 U.S.C. § 360bb.

46. Orphan drug designations covering 11-1F4 (those granted in response to designation request #09-2937 and #09-2903) are collectively referred to herein as “11-1F4 Orphan Drug Designations.” As the owner of the 11-1F4 property rights and know-how, UTRF is the rightful owner of the 11-1F4 Orphan Drug Designations.

47. As the sponsor of the research efforts relating to 11-1F4, Dr. Solomon applied for and received the 11-1F4 Orphan Drug Designations. UTRF’s ownership rights in the 11-1F4 Orphan Drug Designations arises from Dr. Solomon’s and his colleagues’ express, written assignment of all property rights relating to the 11-1F4 technology to UTRC and because all

inventors and researchers working on the development of 11-1F4 were subject to The University of Tennessee Statement of Policy on Patents, Copyrights, and Other Intellectual Property during their work on 11-1F4.

48. In the years immediately subsequent to Dr. Solomon's discovery, UTRC entered into negotiations with several pharmaceutical companies relating to the development of amyloidosis therapies derived from the 11-1F4 antibody. In addition to patent rights, potential industry partners specifically inquired into licensing and utilizing the totality of the 11-1F4 property rights and know-how with the goal of commercializing therapies utilizing the 11-1F4 antibody. For example, at least four separate large, sophisticated pharmaceutical and biopharmaceutical companies engaged in due diligence to explore the potential to enter into an agreement with UTRF regarding the 11-1F4 technology.

#### **THE NATIONAL CANCER INSTITUTE ASSISTS WITH THE DEVELOPMENT OF THE 11-1F4 TECHNOLOGY**

49. In 2011, The University of Tennessee and the National Cancer Institute ("NCI") entered into a Material Transfer Agreement pursuant to the NCI's Experimental Therapeutics Program ("NExT"). Pursuant to this Material Transfer Agreement, Dr. Solomon and his colleagues sent to NCI murine versions of the 11-1F4 antibody along with data from their research. NCI and its subcontractor, AERES Biomedical Ltd., agreed to prepare chimeric versions of the 11-1F4 antibody and transfer back to Dr. Solomon and his team the chimeric version of the 11-1F4 antibody as well as any project data generated through NCI's work on the project. The Material Transfer Agreement confirmed that the original murine version of the 11-1F4 antibody as well as the chimeric version generated by NCI and any data and know-how regarding NCI's work on the 11-1F4 antibody would remain the property of The University of Tennessee. The

University of Tennessee's rights in the 11-1F4 property rights and know-how were transferred to and are owned by UTRF.

50. Pursuant to the NCI NExT Material Transfer Agreement, NCI retained the right to utilize the material and information it received from Dr. Solomon as well as the chimeric antibody product and associated research data generated by NCI; however, only for non-commercial, non-profit purposes relating to NCI's clinical research. NCI further retained the right to supply the chimeric version of the 11-1F4 antibody and provide the research data generated by NCI to third-party non-profit institutions, but solely for non-commercial, non-profit purposes.

51. To the extent any of the 11-1F4 property rights and/or know-how utilized by Caelum were either directly or indirectly supplied by NCI, Caelum's receipt and use of that material was unauthorized by both UTRF and NCI.

#### **DR. SOLOMON'S CONTINUED WORK TO DEVELOP TREATMENTS BASED ON 11-1F4**

52. In 2013, Dr. Solomon began collaborating with Dr. Suzanne Lentzsch of Columbia University to assist with the clinical development of the 11-1F4 technology. At that time, UTRF personnel began working with employees of Columbia University's technology transfer office, Columbia Technology Ventures.

53. UTRF and Columbia Technology Ventures put into place an Inter-Institutional Agreement ("IIA") between UTRF and Columbia University in December 2013. Pursuant to that IIA, Columbia University had a license (and the ability to sublicense) only the patent rights covering the 11-1F4 technology.

54. At the time, there was a granted United States patent (U.S. Patent No. 8,105,594) and a granted Mexico patent relating to certain methods of using the 11-1F4 antibody to treat amyloidosis. The IIA did not provide Columbia University with the ability to sublicense or out-license any of the 11-1F4 property rights or know-how (e.g., the physical antibody materials,

protein sequences, or research data regarding the 11-1F4 antibodies) or to assign any Investigational New Drug applications relating to 11-1F4 nor the 11-1F4 Orphan Drug Designations. The IIA expressly excluded any license to the know-how related to the 11-1F4 antibody held by UTRF.

55. Pursuant to the IIA, any net consideration received by the joint venture between UTRF and Columbia University was to be split evenly between UTRF and Columbia.

56. Dr. Solomon and his colleagues sent to Dr. Lentzsch 11-1F4 antibody materials along with a variety of project data, including the protocol and data used for an Investigational New Drug application with the U.S. Food and Drug Administration.

#### **UTRF AND COLUMBIA NEGOTIATE A POTENTIAL AMENDMENT TO THEIR IIA**

57. Between 2014 and early 2016, UTRF and Columbia Technology Ventures conducted extensive negotiations and exchanged draft agreements relating to an amendment to the IIA that would have covered not only the patent rights relating to the 11-1F4 technology, but to all 11-1F4 physical materials and know-how.

58. In connection with performing diligence supporting a contemplated amendment of the IIA to include a license to the use of the 11-1F4 property rights and know-how, including the chimeric 11-1F4 antibodies along with all associated know-how and data, personnel from Columbia Technology Ventures and UTRF discussed via email and telephonic conference calls on several occasions UTRF's ownership of the 11-1F4 property rights and know-how by way of Dr. Solomon and his colleagues' invention assignment and UTRF's ownership of the chimeric 11-1F4 antibody and associated know-how generated by NCI.

59. At no time during these communications did anyone from Columbia Technology Ventures raise any question or issues challenging UTRF's ownership rights in the property rights and know-how relating to 11-1F4.

## **CAELUM INTERFERES WITH THE ONGOING NEGOTIATIONS BETWEEN COLUMBIA AND UTRF**

60. In late 2015, personnel at Columbia Technology Ventures first raised with UTRF the prospect that a company may be interested in licensing the 11-1F4 technology. The fact that this unnamed potential licensee would want a license to the 11-1F4 property rights and know-how, was explained as an additional reason Columbia University and UTRF should amend the IIA to include all rights to 11-1F4, including property and know-how rights.

61. As UTRF would later learn, during this same time period, Caelum was formed by Fortress Biotech, Inc., and employees and/or agents of Caelum began conducting secret discussions with Columbia University employees and/or agents. UTRF was not a party to these secret discussions.

62. Ultimately, the proposed amendment to the IIA between UTRF and Columbia University was never executed.

63. Caelum was informed of the status of the negotiations between UTRF and Columbia University relating to the potential amendment of the IIA to include all 11-1F4 property rights and know-how such that Columbia University and UTRF would be equal partners on the development of the 11-1F4 technology and share equally in any revenues derived from the commercialization of therapies incorporating the 11-1F4 antibodies.

64. Despite the fact that the IIA was never amended to cover the 11-1F4 property rights and know-how, in 2017, Caelum began publishing press releases containing false statements regarding the ownership of the 11-1F4 technology, false disclosures on its website, and, on information and belief, false disclosures with the U.S. Food and Drug Administration claiming that it had licensed the 11-1F4 technology from Columbia University and that Caelum is now the owner of the 11-1F4 Orphan Drug Designations.

65. On information and belief, Caelum is obligated to indemnify Columbia University for any damages arising out of its commercialization of the 11-1F4 technology and/or any misuse of the 11-1F4 property rights and know-how.

**THE CAELUM-UTRF AGREEMENT PROHIBITS CAELUM FROM USING 11-1F4 PROPERTY WITHOUT UTRF'S WRITTEN AUTHORIZATION**

66. On March 14, 2017, Caelum entered into a Confidentiality Agreement with UTRF and The University of Tennessee so that the parties could exchange information in connection with a potential sponsored research agreement involving UTRF's 11-1F4 technology. Under this March 14, 2017 Agreement, Caelum agreed that it would not, "except to the extent authorized by [UTRF] in writing . . . undertake research, development, or trials with respect to" tangible property relating to the acceleration of amyloid removal by anti-amyloid monoclonal antibodies.

67. While Caelum had UTRF's proprietary research materials prior to the execution of the March 14, 2017 Agreement, that research material is expressly governed by the subsequent March 14, 2017 Agreement: "Notwithstanding the foregoing, it is agreed that [the restrictions entered into in the Confidentiality Agreement] shall not apply to any INFORMATION which . . . is already legally known to the RECEIVING PARTY at the time of disclosure by the DISCLOSING PARTY *and was not acquired, directly or indirectly from the DISCLOSING PARTY . . .*" (emphasis added). Caelum agreed that it would not utilize the research materials and information received "directly or indirectly" from UTRF, even the information received prior to executing the March 14, 2017 Agreement, absent written authorization.

68. In response to the March 2, 2017 email from Columbia explaining that the technology described in the IIA was not licensed despite a purported agreement relating to 11-1F4 between Columbia and Caelum, UTRF indicated to Columbia that it wished to terminate the IIA pursuant to the terms of that agreement.

69. Despite Caelum signing a Confidentiality Agreement agreeing not to utilize 11-1F4 property rights and know-how without written authorization from UTRF, Caelum has proceeded to utilize the 11-1F4 property rights and know-how in an effort to commercialize the technology.

70. UTRF has provided Caelum no written authorization for the use of its 11-1F4 property rights and know-how.

71. Caelum purports to utilize the 11-1F4 property rights and know-how under license from Columbia University.

72. The IIA between Columbia University and UTRF has been terminated, and at no time when the IIA was in effect did Columbia University have authority to license anything other than the patent rights associated with 11-1F4. Columbia University has never had the ability to sublicense or otherwise grant licenses to the use of any of the 11-1F4 property rights and know-how for commercial use.

73. On information and belief, Caelum has used and continues to utilize 11-1F4 materials that are the property of UTRF, including but not limited to: murine 11-1F4 materials; chimeric 11-1F4 materials; cell clones utilized in the production of chimeric 11-1F4 antibodies, and ELISA reagents. On information and belief, Caelum has also used and continues to utilize UTRF's research data, clinical trial and laboratory testing protocols, and documentation incorporated into the Investigational New Drug applications for therapies incorporating the 11-1F4 monoclonal antibody. Caelum's use of the 11-1F4 property rights and know-how is without written authorization from UTRF and Caelum has not compensated UTRF for its use of these materials.

74. Further, on April 5, 2017, Caelum announced in a press release that it had acquired from Columbia University the 11-1F4 Orphan Drug Designations.

75. Columbia University does not and did not own the 11-1F4 Orphan Drug Designations. Caelum is wrongfully and illegally in possession of the 11-1F4 Orphan Drug Designations.

76. Caelum's claims about the 11-1F4 technology being licensed to Columbia by The University of Tennessee have been widely disseminated within the industry to the detriment of UTRF. On March 21, 2017, at the Oppenheimer Healthcare Conference, Gene Kinney, the President and C.E.O. of Prothena Corporation plc, stated, "11-1F4 is an interesting antibody. That antibody started in Allen Solomon's lab at the University of Tennessee, Knoxville. . . . [B]ut ultimately [] that antibody moved to Columbia . . . What we've seen is that that antibody was recently licensed out of Columbia. We saw a press release suggesting that right now, they are in the process of making more clinical material and it looks like expecting to start some clinical trials now in 2018." *Prothena Corporation PLC at Oppenheimer Healthcare Conference*, CCBN FAIR DISCLOSURE WIRE TRANSCRIPT (March 21, 2017) (emphasis added).

77. Caelum has widely published its false claim that it is the licensor of 11-1F4 within the pharmaceutical industry news. Industry press has unwittingly perpetuated the falsehood that Caelum licensed 11-1F4 from Columbia based on a purported transfer of the research program from The University of Tennessee to Columbia. "Startup incubator Fortress Biotech launched Caelum in 2017 after licensing the anti-amyloid antibody they now call CAEL-101 from Columbia based on research by Alan Solomon of the University of Tennessee Graduate School of Medicine. Breaking from the old approach, which focuses on blocking production of new amyloids, he designed the therapy to break up pre-existing amyloid deposits clogging up in tissues to damage patients' organs, particular hearts and kidneys." Amber Tong, *Alexion Lines Up A \$60M Option To Buy Fortress-Incubated Biotech Focused On A Lucrative Rare Blood Disease*, ENDPOINTS

NEWS (Jan. 31, 2019), *available at:* <https://endpts.com/alexion-lines-up-a-60m-option-to-buy-fortress-incubated-biotech-focused-on-a-lucrative-rare-blood-disease/>.

**CAELUM'S UNJUST ENRICHMENT**

78. The entirety of Caelum's business is dedicated to the development of Dr. Solomon's 11-1F4 technology. Caelum solely identifies the 11-1F4 antibody (which it has renamed "CAEL-101") and the clinical trials relating to that antibody as its product pipeline. *See Pipeline, CAELUM BIOSCIENCES WEBSITE, available at:* <https://www.caelumbio.com/pipeline/>.

79. With nothing more than its development of UTRF's 11-1F4 antibody, Caelum's majority shareholder *presently* estimates a "fair value" of Caelum at "\$11.2 million." FORTRESS BIOTECH, INC. SEC FORM 10-Q at 14 (Nov. 12, 2019), *available at:* <http://www.snl.com/Cache/c400965120.html>.

80. Moreover, Caelum's work with the 11-1F4 antibody has enabled it to secure an agreement with Alexion Pharmaceuticals, Inc. entitling Caelum to at least \$60 million with "potential additional payments of up to \$500 million." *Alexion and Caelum Biosciences Announce Collaboration to Develop Targeted Therapy for Light Chain (AL) Amyloidosis, PRESS RELEASE* (Jan. 31, 2019), *available at:* <https://www.businesswire.com/news/home/20190131005293/en/Alexion-Caelum-Biosciences-Announce-Collaboration-Develop-Targeted>.

81. Caelum's founder, Fortress Biotech, recognizes the Alexion agreement as one of Fortress Biotech's two most prominent "Near-term Monetization Opportunities."

## Near-term Monetization Opportunities

 <b>Contingent Acquisition By Cipla</b>	 <b>Contingent Exclusive Acquisition Option Granted To Alexion (Jan. 2019)</b>
<ul style="list-style-type: none"> <li>○ Upon FDA approval and other conditions<sup>1</sup></li> <li>○ \$180 Million aggregate cash purchase; \$166M net of fees (est. \$13.92/share)<sup>1</sup>; FBIO 29% or eligible to receive ~\$48M of the distribution net of fees</li> <li>○ Potential additional payments pursuant to Contingent Value Rights; CVR payout of 10-20% of gross profits<sup>2</sup></li> <li>○ FBIO stands to realize ~\$48M in addition to value of CVRs</li> </ul>	<ul style="list-style-type: none"> <li>○ Alexion purchased minority stock position in Caelum for \$30M, with additional \$30M in funding due upon achievement of development milestones</li> <li>○ Additionally, up to \$500M payable to Caelum shareholders in connection with Alexion option exercise: <ul style="list-style-type: none"> <li>• \$150M - \$200M upfront</li> <li>• Up to \$325M in contingent milestone payments</li> </ul> </li> <li>○ FBIO owns ~40% of Caelum and is eligible to receive ~43% of upfront and milestone proceeds</li> </ul>



<sup>1</sup>subject to conditions described in Avenue public filings

<sup>2</sup>Fortress to receive ~1/3 of CVR royalty

... 9

FORTRESS BIOTECH CORPORATE PRESENTATION at 9 (Nov. 2019), *available at:*  
<http://ir.fortressbiotech.com/Cache/1500125276.PDF?O=PDF&T=&Y=&D=&FID=1500125276&id=4308955>.

### COUNT I BREACH OF CONTRACT

82. UTRF incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

83. On March 14, 2017, UTRF and Caelum entered into an agreement whereby Caelum agreed not to use, *inter alia*, any “tangible materials” for “research, development, or trials” relating to the acceleration of amyloid removal by anti-amyloid monoclonal antibodies “except to the extent authorized by [UTRF] in writing.”

84. The March 14, 2017 Agreement was signed and executed by Caelum’s chief executive officer and the vice president of UTRF.

85. Caelum has used UTRF’s tangible materials without written authorization from UTRF. The tangible materials used by Caelum without authorization are (1) the chimeric 11-1F4 antibody and (2) cell clones utilized in production of the chimeric 11-1F4 antibody (collectively, the “11-1F4 Tangible Materials”).

86. The chimeric 11-1F4 antibody used by Caelum is not a trade secret but is the property of UTRF.

87. The cell clones utilized in production of chimeric 11-1F4 antibodies are not trade secrets but are the property of UTRF.

88. In exchange for agreeing not to use UTRF's 11-1F4 Tangible Materials without written authorization, Caelum received material and information of value from UTRF.

89. Following execution of the March 14, 2017 Agreement, the parties exchanged information and material covered by the Agreement.

90. Caelum breached the March 14, 2017 Agreement it entered into with UTRF through the use of the 11-1F4 Tangible Materials without written authorization.

91. As a direct result of Caelum's improper use of the 11-1F4 Tangible Materials, UTRF has been harmed and will continue to be harmed.

92. For example, Caelum's continued improper use of the 11-1F4 Tangible Materials has prevented UTRF from commercializing the 11-1F4 technology through joint efforts with Columbia University and/or through collaborations with third-party industry partners.

93. As a direct result of Caelum's continued improper use of the 11-1F4 Tangible Materials, UTRF has suffered damages in an amount to be proven at trial.

94. UTRF respectfully requests judgment against Caelum for breach of the March 14, 2017 Agreement arising from Caelum's improper use of the 11-1F4 Tangible Materials.

COUNT II  
CONVERSION

95. UTRF incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

96. Pursuant to Dr. Solomon and Dr. Solomon's research colleagues' express assignment of all rights relating to the 11-1F4 technology to UTRF and pursuant to the Material Transfer Agreement with NCI, UTRF is the sole owner of (1) the chimeric 11-1F4 antibody, (2) cell clones utilized in production of the chimeric 11-1F4 antibody, and (3) the 11-1F4 Orphan Drug Designations (collectively, the "11-1F4 Converted Property").

97. The 11-1F4 Converted Property are tangible, physical property. Specifically, the chimeric 11-1F4 antibody has a fixed physical form. The chimeric 11-1F4 antibody is packaged in vials typically containing 5mL or 10mL of solution. The cell clones utilized in production of chimeric 11-1F4 antibodies also have a tangible, physical form that can be shipped and transferred.

98. The 11-1F4 Converted Property are physical property owned by UTRF.

99. By taking control of the development and commercialization efforts of the 11-1F4 antibody therapies developed by Dr. Solomon and his University of Tennessee colleagues, and on information and belief, by entering into contracts with Columbia University wherein Caelum is provided with the right to control and direct the ongoing clinical trials on the 11-1F4 antibody products under development, Caelum has exercised and continues to exercise dominion and control over the 11-1F4 Converted Property.

100. Further, by improperly effecting the transfer of the 11-1F4 Orphan Drug Designations to its own possession, Caelum is exercising dominion and control over the 11-1F4 Orphan Drug Designations.

101. Caelum has, and at all relevant times, had knowledge that UTRF possesses all right, title, and interest in the 11-1F4 Converted Property.

102. Caelum knows that Dr. Solomon and his University of Tennessee colleagues invented the 11-1F4 technology. Caelum's own website acknowledges Dr. Alan Solomon of The

University of Tennessee Graduate School of Medicine as the “pioneer[]” who developed the 11-1F4 antibody. See *History*, CAELUM WEBSITE, available at: <https://www.caelumbio.com/about/history/>. Caelum refers to the 11-1F4 monoclonal antibody as “[h]is” when discussing Dr. Solomon’s work. *Id.*

103. Caelum had knowledge that Dr. Solomon and his colleagues assigned all rights in the 11-1F4 Converted Property to UTRF.

104. For example, The University of Tennessee Statement of Policy on Patents, Copyrights, and Other Intellectual Property is publicly available (see [https://utrf.tennessee.edu/PDF/IP\\_Policy.PDF](https://utrf.tennessee.edu/PDF/IP_Policy.PDF)) and requires University of Tennessee faculty and staff to assign title to inventions and creations of commercial value to UTRF.

105. Moreover, on information and belief, Caelum was aware that Columbia University had an IIA in place with UTRF regarding the joint development and ownership of the 11-1F4 Converted Property.

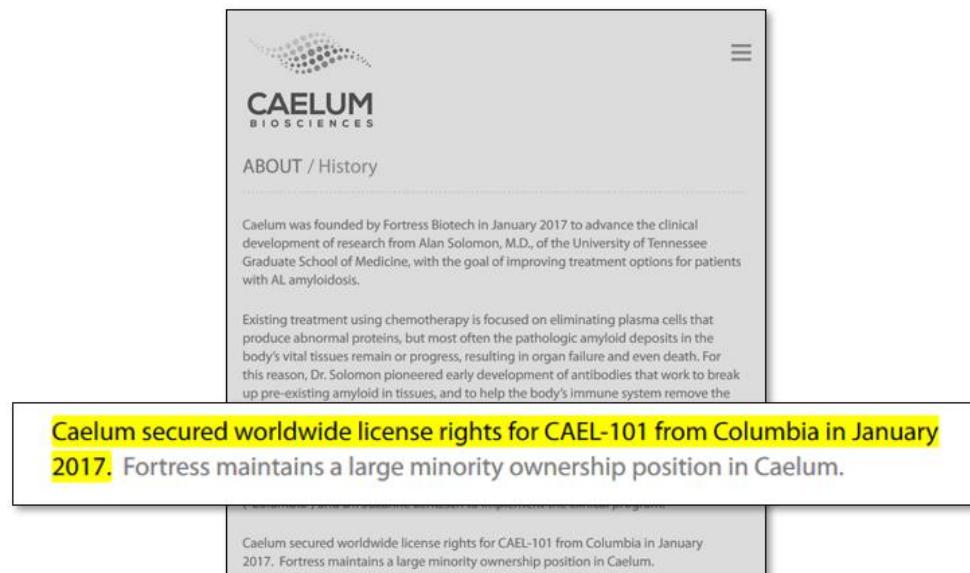
106. On information and belief, Caelum requested that Columbia not amend its IIA with UTRF.

107. Despite Caelum’s knowledge that UTRF is the rightful owner of the 11-1F4 Converted Property, Caelum published false information supporting its claim that it allegedly has the right to utilize the 11-1F4 Converted Property in an effort to commercially develop an 11-1F4 amyloidosis therapy.

108. For example, Caelum falsely claims on its website that “Dr. Solomon’s team transferred the program to Columbia University (‘Columbia’) . . .” *History*, CAELUM WEBSITE, available at: <https://www.caelumbio.com/about/history/>.

109. On information and belief, Caelum knows this statement to be false because Caelum was aware of the joint development efforts between UTRF and Columbia University, as memorialized by the IIA.

110. Caelum also states on its website that “Caelum secured worldwide license rights for CAEL-101 [its renaming of 11-1F4] from Columbia in January 2017.”



*Alexion and Caelum Biosciences Announce Collaboration to Develop Targeted Therapy for Light Chain (AL) Amyloidosis, PRESS RELEASE (January 31, 2019) (emphasis added), available at: <https://www.caelumbio.com/alexion-and-caelum-biosciences-announce-collaboration-to-develop-targeted-therapy-for-light-chain-al-amylodosis>*

111. On information and belief, Caelum knows this statement to be false because it knows that the IIA between Columbia University and UTRF was never amended to include the 11-1F4 Converted Property and that the IIA has been terminated.

112. Despite Caelum’s knowledge that UTRF is the rightful owner of the 11-1F4 Converted Property, and that it is not licensed to use the 11-1F4 Converted Property, Caelum continues to exercise dominion and control over the 11-1F4 Converted Property.

113. On information and belief, the 11-1F4 Converted Property developed by Dr. Solomon are presently within the possession, custody, or control of Caelum.

114. On information and belief, the 11-1F4 Orphan Drug Designations are presently within the possession, custody, or control of Caelum.

115. Caelum's continued unlicensed, uncompensated dominion and control of the 11-1F4 Converted Property is contrary to UTRF's rights, title, and interest in the 11-1F4 Converted Property.

116. As a direct result of Caelum's conversion of UTRF's property, UTRF has been harmed, and will continue to be harmed.

117. As a result of Caelum's conversion of UTRF's property, UTRF has suffered damages in an amount to be proven at trial. UTRF respectfully requests judgment against Caelum for conversion of UTRF's property.

**COUNT III**  
**SLANDER OF TITLE**

118. UTRF incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

119. Pursuant to Dr. Solomon and Dr. Solomon's research colleagues' express assignment of all rights relating to the 11-1F4 technology to UTRF and pursuant to the Material Transfer Agreement with NCI, UTRF is the sole owner of (1) the chimeric 11-1F4 antibody, (2) cell clones utilized in production of the chimeric 11-1F4 antibody, and (3) the 11-1F4 Orphan Drug Designations (collectively, the "11-1F4 Slandered Property").

120. The 11-1F4 Slandered Property are property owned by UTRF.

121. Caelum has repeatedly published in press releases and on its website false statements about the title to the 11-1F4 Slandered Property. Specifically, Caelum has repeatedly published statements suggesting that Columbia University has title and ownership of the 11-1F4

Slandered Property, and that Caelum has obtained a license to the commercial use of the 11-1F4 technology, including the 11-1F4 Slandered Property.

122. Caelum published on its website that “Dr. Solomon’s team transferred the program to Columbia University (‘Columbia’) . . . .” *History*, CAELUM WEBSITE, available at: <https://www.caelumbio.com/about/history/>. This statement is false. Neither Dr. Solomon nor UTRF transferred any ownership interest in the 11-1F4 Slandered Property to Columbia University. Rather, UTRF and Columbia University entered into an IIA for the joint development of the technology. That IIA never provided Columbia University with any ownership interest in the 11-1F4 Slandered Property, and that IIA has been expressly terminated by the parties.

123. Caelum states on its website that “Caelum secured worldwide license rights for CAEL-101 [its renaming of 11-1F4] from Columbia in January 2017.” *Id.* This statement is false. Caelum has not secured worldwide license rights for 11-1F4 from Columbia because Columbia University did not own title to the 11-1F4 Slandered Property.

124. Caelum has submitted false statements regarding its ownership of the 11-1F4 Orphan Drug Designations to the U.S. Food and Drug Administration (FDA).

125. Pursuant to 21 C.F.R. § 316.27(a)(2)(i), (iii), for Caelum to take ownership of the 11-1F4 Orphan Drug Designations, Caelum was required to submit statements to the FDA identifying “[t]he date that the change in ownership or assignment of rights is effective” and “[a] specific description of the rights that have been assigned . . . .” *Id.*

126. Presently, Caelum is listed as the Sponsor for the 11-1F4 Orphan Drug Designations with the FDA.


 U.S. Department of Health & Human Services

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## Search Orphan Drug Designations and Approvals

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Generic Name:	monoclonal antibody 11-1F4
Trade Name:	N/A
Date Designated:	12/11/2009
Orphan Designation:	For use as a therapeutic agent for patients AL amyloidosis.
Orphan Designation Status:	Designated
FDA Orphan Approval Status:	Not FDA Approved for Orphan Indication
Marketing Approval Date:	N/A
Approved Labeled Indication:	
Exclusivity End Date:	N/A
Sponsor:	Caelum Biosciences, Inc. 2 Gansevoort Street 9th Floor New York, New York 10014 USA

The sponsor address listed is the last reported by the sponsor to OOPD.

*Search Orphan Drug Designations and Approvals, FDA WEBSITE, available at:  
<https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm> (last visited Nov. 2019)*  
 (emphasis added).

127. Because Caelum does not own any right, title, and interest, including any valid license to, the 11-1F4 Orphan Drug Designations, on information and belief, Caelum submitted statements containing false information to the FDA in an effort to take possession of the 11-1F4 Orphan Drug Designations.

128. In repeatedly publishing false statements stating that Columbia University, and not UTRF, owned the 11-1F4 technology and suggesting that Caelum enjoys a license to commercially develop the 11-1F4 Slandered Property, Caelum was acting maliciously.

129. Caelum's recognition of The University of Tennessee's role in the development of 11-1F4 and its statement that The University of Tennessee "really initiated the whole development

process of treatments to attack the Amyloid” while simultaneously making false claims about Caelum’s ownership of 11-1F4 is malicious.

130. On information and belief, Caelum knew that the statements it has published clouding UTRF’s ownership interest in the 11-1F4 Slandered Property were false at the time they were published.

131. For example, Caelum knows that Dr. Solomon and his colleagues were employed as full-time faculty members at The University of Tennessee and were subject to The University of Tennessee Statement of Policy on Patents, Copyrights, and Other Intellectual Property. Accordingly, Caelum knew that UTRF owned all right, title, and interest in the 11-1F4 Slandered Property developed by Dr. Solomon and his colleagues.

132. On information and belief, Caelum knew of the joint development efforts between UTRF and Columbia University, as memorialized by the IIA between Columbia University and UTRF.

133. On information and belief, Caelum knows that the IIA between Columbia University and UTRF was never amended to include the 11-1F4 Slandered Property and that the IIA has been terminated.

134. On information and belief, based on the requests of UTRF in connection with negotiations between Columbia University and UTRF regarding a possible amendment of the IIA to include the materials and know-how relating to the development of the 11-1F4 antibody therapies, Caelum decided that it could commercialize the 11-1F4 technology on more favorable financial terms by excluding UTRF from the licensing discussions.

135. Accordingly, rather than allowing Columbia University and UTRF to continue their good-faith negotiations regarding the amendment of the IIA, and rather than engaging directly with

UTRF in negotiations for a license to commercialize the 11-1F4 technology, Caelum, on information and belief, requested that Columbia not amend its IIA with UTRF.

136. On information and belief, Caelum undertook a campaign of publishing false statements suggesting that Columbia University, and not UTRF, had proper ownership and title of the 11-1F4 Slandered Property, and that Columbia University could therefore grant the favorable licensing terms sought by Caelum.

137. On information and belief, Caelum is obligated to indemnify Columbia University for any damages arising out of its commercialization of the 11-1F4 technology and/or any misuse of the 11-1F4 property rights and know-how.

138. As a direct result of Caelum's false statements regarding the ownership of the 11-1F4 Slandered Property (including the 11-1F4 Orphan Drug Designations), UTRF has suffered financial loss.

139. For example, Caelum's public representations that it has licensed all 11-1F4 property and that it owns the 11-1F4 Orphan Drug Designations has prevented UTRF from commercializing the 11-1F4 technology through joint efforts with Columbia University and/or through collaborations with third-party industry partners.

140. Further, Caelum's false statements to the pharmaceutical industry and the U.S. FDA necessitated this litigation. If UTRF simply resorted to publishing statements of its own insisting that it indeed is the rightful owner of the 11-1F4 Slandered Property, UTRF would not be able to enjoy its full right, title, and interest in the 11-1F4 Slandered Property. Without filing the instant action, UTRF risked losing its ability to recover damages for the misuse of its proprietary technology by operation of law. Accordingly, UTRF was required to hire counsel and undertake

the costs of attorneys' fees and litigation expenses to protect its right, title, and interest in the 11-1F4 Slandered Property (including the 11-1F4 Orphan Drug Designations).

141. Caelum forced UTRF into Court; UTRF's attorneys' fees and litigation expenses in litigating this case were directly and proximately caused by Caelum's malicious publication of false statements regarding title to the 11-1F4 Slandered Property.

142. As a direct result of Caelum's malicious publication of false statements regarding title to the 11-1F4 Slandered Property, UTRF has suffered damages in an amount to be proven at trial.

143. UTRF respectfully requests judgment against Caelum for slander of title due to its malicious publication of false statements regarding title to the 11-1F4 Slandered Property.

**COUNT IV**  
**TORTIOUS INTERFERENCE WITH BUSINESS RELATIONSHIP WITH COLUMBIA UNIVERSITY**

144. UTRF references and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

145. Prior to Caelum's formation, UTRF had an existing business relationship with Columbia University. UTRF and Columbia University executed an Inter-Institutional Agreement ("IIA") in December 2013 – approximately a year and a half before Caelum was formed as a corporation with the Delaware Secretary of State.

146. Caelum has, and at all relevant times, had knowledge that UTRF had a business relationship with Columbia University.

147. On information and belief, Caelum was aware that Columbia University had an IIA in place with UTRF regarding the joint development of the 11-1F4 technology.

148. On information and belief, Caelum requested that Columbia not amend its IIA with UTRF.

149. Caelum intended to cause a breach or termination in the business relationship between Columbia and UTRF. Specifically, Caelum's C.E.O. stated that in 2016 that Caelum caused Columbia to enter into a secret option agreement relating to the commercialization of the 11-1F4 antibody.

150. Prior to Caelum conducting secret meetings with Columbia University and Columbia Technology Ventures personnel, negotiations toward an amended IIA that would make Columbia University and UTRF partners in any license to the 11-1F4 technology were proceeding in good-faith toward the common goal of advancing the 11-1F4 technology to the benefit of patients suffering with amyloidosis and to the benefit of The University of Tennessee and Columbia University.

151. For example, in February 2016, a Columbia Technology Ventures employee emailed UTRF personnel a draft amendment to the IIA that would have provided UTRF with a share of proceeds recognized by the joint venture based on any licenses to 11-1F4. In that draft amendment to the IIA, Columbia proposed a definition of the licensed 11-1F4 Know-How as, "Any Know-How associated with the Patent Rights and Materials related to the 11-1F4 as a diagnostic or therapeutic."

152. In a subsequent email, also in February 2016, Columbia Technology Ventures explained that Columbia desired to be partners with UTRF with respect to any subsequent modifications of the 11-1F4 technology. The draft amendment to the IIA circulated by Columbia Technology Ventures in February 2016 maintained the original revenue split, with each of Columbia and UTRF receiving 50% of the net consideration paid for a license to the 11-1F4 technology.

153. Despite these repeated, positive communications indicating interest in amending the IIA to include a license to all 11-1F4 materials and know-how, the IIA was never amended.

154. Contemporaneous to UTRF and Columbia negotiating the amended IIA, Caelum sought and was successful in entering into a secret option agreement with Columbia that illegally sought to deprive UTRF of its rights in and to the 11-1F4 property and know-how.

155. On information and belief, based on UTRF's requests in negotiations with Columbia University regarding a possible amendment of the IIA, Caelum decided that it could commercialize the 11-1F4 technology on more favorable financial terms by excluding UTRF from the licensing discussions.

156. Accordingly, rather than allowing Columbia University and UTRF to continue their good-faith negotiations regarding the amendment of the IIA, and rather than engaging directly with UTRF in negotiations for a license to commercialize the 11-1F4 technology, Caelum requested that Columbia cease negotiations with UTRF and not agree to amend the IIA.

157. On information and belief, Caelum's orchestration of its 2016 secret option agreement with Columbia was intended by Caelum to cause the termination of the business relationship between Columbia and UTRF.

158. Caelum's interference in the Columbia / UTRF business relationship was directed at causing harm to UTRF. Under the 2016 secret option agreement and the March 14, 2017 Agreement between Caelum, UTRF, and The University of Tennessee, Caelum orchestrated the unlawful conversion and misappropriation of UTRF's property and trade secrets. The injury to UTRF was undertaken with malicious intent by Caelum as Caelum contemporaneously recognized in interviews and press releases UTRF's singularly important role in the development of the very property and trade secrets of which Caelum sought to deprive UTRF.

159. Caelum's improper actions in interfering with UTRF and Columbia's business relationship included slandering UTRF's title and having Columbia purportedly grant Caelum rights to UTRF's property without UTRF's permission.

160. Highlighting Caelum's knowledge of its own improper actions in interfering with UTRF and Columbia's business relationship with respect to the amendment of the IIA is the fact that, on information and belief, Caelum is obligated to indemnify Columbia University for any damages arising out of its commercialization of the 11-1F4 technology and/or any misuse of the 11-1F4 property rights and know-how.

161. Caelum's interference in the business relationship between Columbia University and UTRF has prevented UTRF from commercializing the 11-1F4 technology through joint efforts with Columbia University.

162. Caelum's tortious interference in UTRF's business relationship with Columbia is based on inducing Columbia to do business with Caelum while excluding UTRF. This inducement was accomplished not by offering the Columbia confidential information in order to induce the relationship but by Caelum seeking to do business with Columbia to the injury of UTRF.

163. As a direct result of Caelum's interference with UTRF's business relationship with Columbia University, UTRF has suffered pecuniary loss in an amount to be proven at trial.

164. UTRF respectfully requests judgment against Caelum for tortious interference with UTRF's business relationship with Columbia University.

**COUNT V**  
**TORTIOUS INTERFERENCE WITH BUSINESS RELATIONSHIP WITH INDUSTRY PARTNERS**

165. UTRF references and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

166. Prior to Caelum's formation, UTRF had existing business relationships with large and mid-size companies within the pharmaceutical industry interested in commercializing the 11-1F4 technology. For example, at least four separate large, sophisticated pharmaceutical and biopharmaceutical companies engaged in due diligence to explore the potential to enter into an agreement with UTRF regarding the 11-1F4 technology.

167. In connection with UTRF's Inter-Institutional Agreement with Columbia University relating to UTRF's 11-1F4 technology, UTRF disclosed the existence of specific pharmaceutical companies who had signed confidentiality agreements and/or term sheets with UTRF relating to these companies' desire to commercialize the 11-1F4 technology.

168. On information and belief, Columbia University disclosed to Caelum the specific pharmaceutical companies who had expressed interest in commercializing the 11-1F4 technology to UTRF. Alternatively, on information and belief, Columbia University disclosed to Caelum that there were third-party pharmaceuticals who were also interested in commercializing the 11-1F4 technology without disclosing the specific identities of those third-party pharmaceutical companies to Caelum.

169. Caelum was aware that Columbia University had an IIA in place with UTRF regarding the joint development of the 11-1F4 technology.

170. Caelum requested that Columbia not amend its IIA with UTRF.

171. For example, Caelum falsely claims on its website that "Dr. Solomon's team transferred the program to Columbia University ('Columbia') . . ." *History*, CAELUM WEBSITE, available at: <https://www.caelumbio.com/about/history/>.

172. On information and belief, Caelum knows this statement to be false because Caelum was aware of the joint development efforts between UTRF and Columbia University, as memorialized by the IIA.

173. Caelum knows that the IIA between Columbia University and UTRF was never amended to include the 11-1F4 property rights and know-how and that the IIA has been terminated.

174. Prior to Caelum conducting secret meetings with Columbia University and Columbia Technology Ventures personnel, negotiations toward an amended IIA that would make Columbia University and UTRF partners in any license to the 11-1F4 property rights and know-how were proceeding in good-faith toward the common goal of advancing the 11-1F4 technology to the benefit of patients suffering with amyloidosis and to the benefit of The University of Tennessee and Columbia University.

175. For example, in February 2016, a Columbia Technology Ventures employee emailed UTRF personnel a draft amendment to the IIA that would have provided UTRF with a share of proceeds recognized by the joint venture based on licenses to any 11-1F4 property rights and know-how. In that draft amendment to the IIA, Columbia proposed a definition of the Know-How as, “Any Know-How associated with the Patent Rights and Materials related to the 11-1F4 as a diagnostic or therapeutic.”

176. In a subsequent email also in February 2016, Columbia Technology Ventures explained that Columbia desired to be partners with UTRF with respect to any subsequent modifications of the 11-1F4 technology. The draft amendment to the IIA circulated by Columbia Technology Ventures in February 2016 maintained the original revenue split, with each of Columbia and UTRF receiving 50% of the net consideration paid for a license to the 11-1F4 technology.

177. Despite these repeated, positive communications indicating interest in amending the IIA to include a license to all 11-1F4 property and know-how, the IIA was never amended.

178. On information and belief, based on UTRF's requests in negotiations with Columbia University regarding a possible amendment of the IIA, Caelum decided that it could commercialize the 11-1F4 technology on more favorable financial terms by excluding UTRF from the licensing discussions.

179. Accordingly, rather than allowing Columbia University and UTRF to continue their good-faith negotiations regarding the amendment of the IIA, and rather than engaging directly with UTRF in negotiations for a license to commercialize the 11-1F4 technology, Caelum, on information and belief, requested that Columbia not amend its IIA with UTRF.

180. Caelum then undertook a campaign of publishing false statements suggesting that Columbia University, and not UTRF, had proper ownership and title of the 11-1F4 property rights and know-how, and that Columbia University could therefore grant the favorable licensing terms sought by Caelum.

181. On information and belief, Caelum intended to prevent UTRF from pursuing business relationships with interested third-party pharmaceutical companies by clouding UTRF's title to the 11-1F4 property rights and know-how, as well as the 11-1F4 Orphan Drug Designations.

182. As a direct result of Caelum's interference with UTRF's business relationship with third-party pharmaceutical companies interested in commercializing the 11-1F4 technology, UTRF has suffered pecuniary loss in an amount to be proven at trial.

183. Caelum's tortious interference in UTRF's business relationships with third-party pharmaceutical companies is based on inducing Columbia to do business with Caelum so UTRF would be unable to enter into business relationships with third-party pharmaceutical companies.

This inducement was accomplished not by offering the Columbia confidential information in order to induce the relationship but by Caelum seeking to do business with Columbia to the injury of UTRF's relationships with third-party pharmaceutical companies.

184. UTRF respectfully requests judgment against Caelum for tortious interference with UTRF's business relationship with third-party pharmaceutical companies interested in commercializing the 11-1F4 technology.

**COUNT VI**  
**UNJUST ENRICHMENT**

185. UTRF references and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

186. Defendant Caelum has entered into licensing and other agreements relating to the use and commercialization of the 11-1F4 property rights, know-how, and the 11-1F4 Orphan Drug Designations.

187. The entirety of Caelum's business is dedicated to the development of Dr. Solomon's 11-1F4 technology. Caelum's website states: "Caelum was founded by Fortress Biotech in January 2017 to advance the clinical development of research from Alan Solomon, M.D., of the University of Tennessee Graduate School of Medicine, with the goal of improving treatment options for patients with AL amyloidosis." *About Caelum Biosciences*, CAELUM BIOSCIENCES WEBSITE (last visited November 2019), available at: <https://www.caelumbio.com/about/history/>. Upon its founding, Caelum's parent company, Fortress Biotech, announced "the formation of a new subsidiary company, Caelum Biosciences, Inc., to advance the development of CAEL-101 (11-1F4)." *Fortress Biotech forms a new subsidiary, Caelum Biosciences, Inc., to develop a novel treatment for AL Amyloidosis*, PRESS RELEASE (Jan. 4, 2017) (emphasis added); see also *Pipeline*, CAELUM BIOSCIENCES WEBSITE (last

visited February 2020), *available at*: <https://www.caelumbio.com/pipeline/> (identifying only “CAEL-101,” (Caelum’s renaming of 11-1F4) as the only product in Caelum’s product pipeline).

188. With nothing more than its development of UTRF’s 11-1F4 antibody, Caelum’s majority shareholder *presently* estimates a “fair value” of Caelum at “\$11.2 million.”

FORTRESS BIOTECH, INC. AND SUBSIDIARIES Non-Controlling Consolidated Financial Statements (Unaudited)		
B. Property and Equipment		
Former property and equipment consisted of the following:		
(In thousands)	September 30, 2019 (Unaudited)	December 31, 2018
Computer equipment	\$ 0	442
Software and licenses	0	1,124
Inventory & supplies	0	3,985
Less-than-one-year leasehold improvements	0.12	0.23
Capitalized expenditures (1)	0.4	0.51
Total property and equipment	10.12	5,558
Less Accumulated depreciation	(2.87)	(2,985)
Property and equipment, net	\$ 7.25	\$ 2,573

Item 3. Balance in the financing cell processing facility  
Former depreciation expense for the three months ended September 30, 2019 and 2018, was approximately \$1.1 million and \$0.4 million, respectively, and was recorded as fixed assets and depreciation expense and general and administrative expense in the Consolidated Statements of Income.  
Estimated depreciation expense for the year ended ended September 30, 2019 and 2018, was approximately \$1.4 million and \$0.2 million, respectively, and

#### Fair Value of Caelum

The Company valued its investment in Caelum in accordance with ASC Topic 820, *Fair Value Measurements and Disclosures*, and estimated the fair value to be \$11.2 million based on a per share value of \$1,549. The following inputs were utilized to derive the value: risk free rate of return of 2.24%, volatility of 70% and a discount for lack of marketability of 27.9%.

The Caelum warrant liability and convertible notes did not exist as of September 30, 2019. A measure of the weighted average (as aggregated) inputs used in the fair value measurement is as follows:	
Risk-free interest rate	2.24%
Expected dividend yield	—
Expected term to payoff	1.00—1.00
Expected volatility	70%

FORTRESS BIOTECH, INC. SEC FORM 10-Q at 14 (Nov. 12, 2019) (emphasis added), *available at*: <http://www.snl.com/Cache/c400965120.html>.

189. Moreover, Caelum’s work with the 11-1F4 antibody has enabled it to secure an agreement with Alexion Pharmaceuticals, Inc. entitling Caelum to at least \$60 million with “potential additional payments of up to \$500 million.” *Alexion and Caelum Biosciences Announce Collaboration to Develop Targeted Therapy for Light Chain (AL) Amyloidosis*, PRESS RELEASE (Jan. 31, 2019), *available at*: <https://www.caelumbio.com/alexion-and-caelum-biosciences-announce-collaboration-to-develop-targeted-therapy-for-light-chain-al-amylodosis/>.

190. Caelum has therefore enjoyed significant consideration paid by Alexion Pharmaceuticals, Inc. relating to the commercialization of the 11-1F4 technology while failing to compensate UTRF.

191. Caelum has not paid any portion of the revenue it has derived from the commercialization of the 11-1F4 technology to UTRF.

192. Allowing Caelum to collect revenue directly attributable to its possession and use of the 11-1F4 property rights, know-how, and the 11-1F4 Orphan Drug Designations is unjust and wrongly enriches Caelum.

193. Caelum's breach of its March 14, 2017 Agreement with UTRF, its tortious conversion and slander of title of the 11-1F4 Tangible Materials and the 11-1F4 Orphan Drug Designations, and Caelum's tortious interference with UTRF's business relationships with both Columbia University and third-party pharmaceutical companies interested in the commercialization of the 11-1F4 technology have resulted in the unjust enrichment of Caelum at the expense of UTRF in an amount to be proven at trial.

194. UTRF respectfully requests judgment against Caelum for any and all unjust enrichment which Caelum has gained as a result of its illegal actions described herein.

**COUNT VII**  
**MISAPPROPRIATION OF TRADE SECRETS UNDER**  
**THE TENNESSEE UNIFORM TRADE SECRETS ACT (TENN. CODE ANN. § 47-25-1701 ET SEQ.)**

195. UTRF references and incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

196. Caelum has misappropriated UTRF's trade secrets. Specifically, Caelum misappropriated the following confidential information: confidential know-how associated with the development and use of the 11-1F4 antibody products, including the results, data, and information relating to antigens, antibodies, and cell lines necessary or useful for development or commercialization of the 11-1F4 antibody products, as well as research data prepared by University of Tennessee researchers utilized in the Investigational New Drug application file submitted with the U.S. Food and Drug Administration in connection with an approval request for

11-1F4 therapies (including IND No. 117,316 entitled, “Chimeric Monoclonal Antibody 11-1F4”) (collectively, the “11-1F4 Trade Secrets”).

197. The 11-1F4 Trade Secrets have value independent of any 11-1F4 property rights. Specifically, the trade secrets are valuable data that enable the development of a drug product. Caelum was able to use the 11-1F4 Trade Secrets to obtain a substantial monetary investment from Alexion.

So the reason we're really excited about CAEL-101 is it's an antibody that is specifically designed to bind to the kappa and lambda light chains of immunoglobulin. And when we looked at the data that the company had generated and researchers had generated in the University of Tennessee and at Columbia University and we looked at the in vivo imaging data, that gave us a lot of confidence because we could actually see that this antibody is binding to the amyloid deposits in the organs.

*Alexion Pharmaceuticals, Inc. Investor Day Presentation, CCBN FAIR DISCLOSURE WIRE TRANSCRIPT (March 20, 2019) (emphasis added).*

198. Caelum has recognized the independent value of the 11-1F4 Trade Secrets as it previously paid Columbia for these trade secrets in a 2017 Agreement.

199. The value of the 11-1F4 Trade Secrets is based on the information not being generally known. Should the 11-1F4 Trade Secrets be generally known, possession of the 11-1F4 Trade Secrets would not confer a competitive advantage or economic advantage on a drug developer.

200. The 11-1F4 Trade Secrets have been subject to significant efforts to maintain their secrecy. For example, the filing of the 11-1F4 Trade Secrets as part of an investigational new drug application is subject to significant confidentiality restrictions. *See generally* 21 C.F.R. §§ 601.50-601.51 (providing for extensive confidentiality protections for any [Investigational New Drug application] as well as “all data” and the “master files, and other related submissions” associated with any such application filed with the U.S. Food and Drug Administration).

201. Caelum and Columbia have made efforts to maintain the secrecy of the 11-1F4 Trade Secrets by entering into confidentiality agreements that restrict the distribution of the 11-1F4 Trade Secrets. These secrecy efforts include provisions in a 2017 Agreement between Caelum and Columbia.

202. In violation of Tenn. Code Ann. § 45-25-1702, Caelum misappropriated the 11-1F4 Trade Secrets through improper means by having Columbia provide the 11-1F4 Trade Secrets despite knowing that UTRF was the owner of the 11-1F4 Trade Secrets and had not authorized Caelum's access to or appropriation of the 11-1F4 Trade Secrets.

203. Caelum knew that the 11-1F4 Trade Secrets were the property of UTRF and its access was unauthorized. Specifically, Caelum was aware that the data was generated by The University of Tennessee and that there was not a valid assignment by the University or UTRF of the 11-1F4 Trade Secrets to Caelum.

204. Caelum's misappropriation of UTRF's 11-1F4 Trade Secrets was willful and malicious as defined by Tenn. Code Ann. §§ 47-25-1704(b) and 47-25-1705(3).

205. Contemporaneous to UTRF and Columbia negotiating an amendment to their IIA, Caelum sought and was successful in entering into a secret option agreement with Columbia that illegally sought to obtain UTRF's 11-1F4 Trade Secrets unbeknownst to UTRF.

206. On information and belief, based on UTRF's requests in negotiations with Columbia University regarding a possible amendment of the IIA, Caelum decided that it could commercialize the 11-1F4 technology on more favorable financial terms by excluding UTRF from the licensing discussions.

207. Accordingly, rather than allowing Columbia University and UTRF to continue their good-faith negotiations regarding the amendment of the IIA, and rather than engaging directly with

UTRF in negotiations for a license to commercialize the 11-1F4 technology, Caelum requested that Columbia cease negotiations with UTRF and not agree to amend the IIA.

208. Caelum's continued unlicensed, uncompensated misappropriation of the 11-1F4 Trade Secrets is contrary to UTRF's rights, title, and interest in the 11-1F4 Trade Secrets.

209. As a direct result of Caelum's misappropriation of UTRF's 11-1F4 Trade Secrets, UTRF has been harmed, and will continue to be harmed.

210. As a result of Caelum's misappropriation of UTRF's 11-1F4 Trade Secrets, UTRF has suffered damages in an amount to be proven at trial. UTRF respectfully requests judgment against Caelum for misappropriation of UTRF's trade secrets.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor and against Caelum, including:

- A. A finding that Caelum has breached its 2017 Agreement with UTRF by utilizing the 11-1F4 Tangible Property owned by UTRF and caused damages to UTRF in an amount to be proven at trial, together with interest and costs as fixed by the Court;
- B. A finding that Caelum is liable for conversion of UTRF's 11-1F4 Converted Property and caused damages to UTRF in an amount to be proven at trial, together with interest and costs as fixed by the Court;
- C. A finding that Caelum is liable for slander of title of UTRF's 11-1F4 Slandered Property and caused damages to UTRF in an amount to be proven at trial, together with UTRF's attorneys' fees and costs associated with this action and interest and costs as fixed by the Court;
- D. A finding that Caelum is liable for tortious interference with UTRF's business relationship with Columbia University and caused damages to UTRF in an amount to be proven at trial, together with interest and costs as fixed by the Court;
- E. A finding that Caelum is liable for tortious interference with UTRF's business relationship with third-party pharmaceutical companies interested in commercializing the 11-1F4 technology and caused damages to UTRF in an amount to be proven at trial, together with interest and costs as fixed by the Court;
- F. A finding that Caelum has been unjustly enriched at UTRF's expense and

- caused damages in an amount to be proven at trial, together with interest and costs as fixed by the Court; and
- G. A finding pursuant to that Caelum utilized improper means to misappropriate UTRF's 11-1F4 Trade Secrets from UTRF and caused damages to UTRF in an amount to be proven at trial, together with exemplary damages not exceeding twice UTRF's damages, UTRF's attorneys' fees and costs associated with this action and interest and costs as fixed by the Court.

**JURY TRIAL DEMANDED**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, University of Tennessee Research Foundation hereby requests a trial by jury of any issues so triable by right.

Dated: March 6, 2020

Respectfully submitted,

s/Wayne A. Ritchie II

Wayne A. Ritchie II, BPR #013936

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*Attorneys for Plaintiff University of  
Tennessee Research Foundation*

**Certificate of Service**

The undersigned hereby certifies that on this 6th day of March, 2020, the foregoing was electronically filed with the Clerk of Court using the CM/EFC filing system, which will electronically serve same on all counsel of record.

s/Wayne A. Ritchie II

WAYNE A. RITCHIE II